

**Patient Safety and Legal Challenges:
Disclosure of Medical Error, Class Actions, and Reporting Systems**

by

Tim Wöffen

A thesis submitted in conformity with the requirements
for the degree Masters of Law (LL.M.)
Graduate Department of Law
University of Toronto

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Your file Votre référence
ISBN: 978-0-494-45094-9
Our file Notre référence
ISBN: 978-0-494-45094-9

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Abstract

This paper explores some of the recent legal developments in Canada and the United States with respect to patient safety. It starts off with a critique of the current “patient safety approach” or “systems approach” to medical error which is the theoretical basis for many reform efforts. A critique of the tort system follows. Within the adversarial tort system, the disclosure of errors to patients remains difficult and requires substantial legal changes. A promising development is the increased use of class actions in Canada to address systemic errors. The patient safety movement has also led to the development of a variety of reporting systems. As a means of safety-research and quality-management, it is their goal is to detect unsafe conditions, preferably before harmful medical errors occur. In the United States, legal protections are increasingly used to create trust in confidential reporting and to uncouple reporting systems from other procedures.

Acknowledgements

I gratefully thank my supervisor Professor Trudo Lemmens for his guidance, comments and kind encouragement. His courses Medical Law and Public Health Law have been a great source of inspiration. Furthermore, Professor Colleen Flood's workshop on Health Law and Policy, and the National Health Law Conference 2007 offered unique opportunities to learn more about emerging issues in Health Law. I thank my SJD Advisors Revital Goldhar and Meital Pinto for their comments and the staff of the Faculty of Law and other institutions at the University of Toronto. I like to thank Anjali Chaudhri heartily for proof-reading my thesis. I feel grateful for meeting and becoming friends with students from Canada and from around the world in the great city of Toronto.

I am deeply indebted to Professor Christian Katzenmeier and the Institute for Medical Law at the University of Cologne and Professor Heinz-Peter Mansel for supporting my wish to pursue graduate studies at UofT. I thank the German Academic Exchange Service (DAAD) for the generous support and I encourage Canadian students to apply for scholarships and grants to study and research in Germany (www.daad.org). Finally, I would like to thank my dear parents, Hilde and Bernhard, my brother Daniel and my sister Nora for their love and support.

Tim Wöffen
Toronto, Sep. 3, 2008

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I. Introduction

Almost a decade ago, the Institute of Medicine (IOM) dropped a bombshell with its report “To Err is Human” stating that 44,000 to 98,000 patients in the United States die from medical errors each year.¹ The underlying “patient safety approach” or “systems approach” to medical error became the major theoretical basis for many legal reform efforts. Recently, critiques of the systems approach are emerging. The accuracy of the statistics is uncertain and attempts to quantify medical errors are difficult. In this paper, I also include a conceptual critique of the systems approach. The tort-based medical malpractice system in Canada faces many challenges in responding to patient safety ideas. First, I will point out that the disclosure of medical errors to patients is still difficult and requires substantial legal changes. On a positive note, I will show that class actions are increasingly used in Canada as a powerful tool to shed light on systemic deficiencies and create public awareness for patient safety. Moving on, I will discuss how the patient safety movement has also led to the development of a variety of reporting systems. As a means of safety-research and quality-management, reporting systems aim to detect unsafe conditions, preferably before harmful medical errors occur. The paper will outline some of the structural elements of the systems. It will also give a discussion on doubts associated with the efficacy of reporting systems that require further research. Recent efforts in the United States address the challenge to create a coherent framework and to protect reporters efficiently under the federal *Patient Safety and*

¹ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) 31.

Quality Improvement Act (2005). Legal protections are increasingly used to create trust in confidential reporting and to uncouple reporting systems from other procedures.

II. The Patient Safety Approach to Medical Error

Patient safety means freedom from accidental injury in healthcare.² It has always been a cornerstone of the medical training and practice to not worsen the patient's condition: "First do no harm!" Almost a decade ago, the term "patient safety" became a new buzzword in this context and a major issue of public interest when the Institute of Medicine's report "To Err is Human" (1999) found that 44,000 to 98,000 patients in the United States die from adverse events each year.³ Given the highest estimate of 98,000, U.S. healthcare "kills" 268 patients every day. Even if only the lower estimate is accurate, medical errors would be the eighth leading cause of death in the U.S. above fatal motor-vehicle accidents, breast cancer and HIV/AIDS.⁴ The study shook the myth of the physicians' infallibility and safe healthcare. It showed that healthcare related injury is a common, widespread phenomenon.

² *Ibid.* at 18; the Canadian National Steering Committee on Patient Safety in Canada had adopted a different definition emphasizing the process rather than the result: "Patient Safety: The state of continually working toward the avoidance, management and treatment of unsafe acts within the health-care system", see in National Steering Committee on Patient Safety "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care" (2002), available online: <<http://rcpsc.medical.org/publications/>> at 37; It is interesting to note that Canadian criminal courts have developed a certain definition of "safety" in the context of "criminal harassment", section 264 Canadian Criminal Code: "Safety" means "more that freedom from physical harm. It includes a freedom from fear of mental or emotional or psychological trauma." see *R. v. Gowling* [1994] O.J. No. 1696, *R. v. Lafreniere* [1994] O.J. No. 437 cited in *R. v. Theysen*, [1996] A.J. No. 788.

³ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) "To Err is Human – Building a Safer Health System" (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000), 31.

⁴ National Steering Committee on Patient Safety "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care" (2002), available online: <<http://rcpsc.medical.org/publications/>> at 46.

In Canada, a National Steering Committee on Patient Safety created a national strategy to improve patient safety in Canadian healthcare in 2001.⁵ The Patient Safety Institute was established in 2002⁶ and the findings of the Canadian Adverse Events Study were released in 2004: in the year 2000 between 9,250 and 23,750 Canadians admitted to acute care hospitals died as a result of preventable adverse events.⁷ Further studies indicate that the situation is similar in many other healthcare systems of the industrialized world. Studies were carried out in Denmark, the United Kingdom, New Zealand, and Australia. However, the results are not always easy to compare because of slightly different methodologies. Rates of adverse events per hospital admissions vary from 3.7% in the U.S., to 7.5% in Canada, 9% in Denmark, 11.7% in the United Kingdom, 12.9% in New Zealand, and 16.6% in Australia.⁸ In October 2004, the patient safety movement reached a climax with the formation of the “World Alliance for Patient Safety” at the World Health Organization (WHO) characterizing medical error as a public health hazard of global scale.⁹

⁵ National Steering Committee on Patient Safety “Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” (2002), available online: <<http://rcpsc.medical.org/publications/>>.

⁶ Its website is <<http://www.patientsafetyinstitute.ca/index.html>>.

⁷ Ross G. Baker, (et al) “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada” (2004) 170 (11) JAMC, 1678 at 1684.

⁸ See in form of a table in Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 11 of Appendix 1.

⁹ World Alliance for Patient Safety at the World Health Organization (WHO) <<http://www.who.int/patientsafety/worldalliance/en/>>.

A. Critique of the Statistics

The statistics in the U.S. of 44,000 to 98,000 deaths a year has been criticised as exaggerated and unreliable¹⁰. The span of 44,000 to 98,000 is indeed a vague finding considering that 98,000 is more than twice the lower estimate of 44,000. The two different numbers result out of extrapolations based on two studies, the Harvard Medical Practice Study in the state of New York, and an adverse events study in Utah and Colorado, which both reviewed medical charts of hospitals.¹¹ Both studies have been criticised for flaws and contingencies in their methodologies.¹² However, the findings have also been defended as being modest because medical charts may not always contain notes on adverse events. Also, the studies solely focused on adverse events in the hospital setting and thereby excluded data on adverse events in ambulatory care. These uncertainties have led to difficulties in measuring progress in patient safety today. It is

¹⁰ A good overview of the critique of the statistics can be found in Maxine M. Harrington, "Revisiting Medical Error: Five Years after the IOM Report, Have Reporting Systems made a Measurable Difference?" (2005) 15 Health Matrix 329-382 at 332-351 "Clinical Estimates of Medical Error: The Correct Diagnosis?" Raymond DeVries, Trudo Lemmens, Charles Bosk "The Subjectivity of Objectivity: The Social, Cultural and Political Shaping of Evidence-Based Medicine" in Belinda Bennett, Terry Carney and Isabel Karpin, eds., *The Brave New World of Health* (Sydney: Federation Press, 2008). Available online:

<http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1126443>, 19.

¹¹ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) "To Err is Human – Building a Safer Health System" (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000), at 1; T. A. Brennan, L. L. Leape, N. M. Laird, (et al) "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I." (1991) 324 *New England Journal of Medicine* 370-376 and L. L. Leape, T. A. Brennan, N. M. Laird, (et al) "The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II." (1991) 324 *New England Journal of Medicine* 377-384; Eric J. Thomas, David M. Studdert, Helen R. Burstin, E. John Orav, Timothy Zeena, Elliott J. Williams, K. Mason Howard, Paul C. Weiler, Troyen A. Brennan, "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado" (2000) 38 *Medical Care* 261-271.

¹² Harrington, *supra* note 10, at 332-351, Carol Brayshaw Longwell "Pennsylvania's Patient Safety Authority: Another Perspective" (2005) 63 *Pennsylvania Bar Association Quarterly* 63 at 65.

hard to recognize progress when there is no reliable baseline.¹³ The IOM report stated in 1999 that it should be the goal to cut the number of errors in half within 5 years.¹⁴ Without a reliable benchmark we do not know whether this goal was achieved.

B. Value of the Patient Safety Concept

The IOM report remains important for its intriguing conceptual ideas and policy considerations. The high number of adverse events was only a starting point for rethinking the concept of medical error. The report claimed that most adverse events are not due to individual negligence of physicians. More commonly, errors were caused by faulty systems, processes, and conditions that led people to make mistakes. A policy change has been demanded from a “culture of blaming individuals” towards a “systems approach” to medical error, and towards a “culture of safety” that balances accountability and safety needs.¹⁵ One goal is to identify and change environmental factors and unsafe conditions that predispose humans to err rather than focusing solely on deterrence and holding individuals “at the sharp end” accountable.¹⁶ Instead of “searching and culling bad apples” intensively with malpractice suits and disciplinary proceedings, finding

¹³ *Ibid.* at 67.

¹⁴ Kohn, Linda T.; Corrigan, Janet M.; Donaldson, Molla S. (eds.) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) at 4.

¹⁵ Instructively James Reason, “Human Error: Models and Management” (2000) 320 *BMJ* 768-770; Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate, 1997) at 191 and Dekker *Just Culture: Balancing Safety and Accountability* (Aldershot: Ashgate Publishing Limited, 2007); see also Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 3 referring to it as “person-centered” and “systems-centered”.

¹⁶ National Steering Committee on Patient Safety “Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” (2002), available online: <<http://rcpsc.medical.org/publications/>> at 8.

latent systemic causes is now considered just as important. Advocates for patient safety state that while one cannot fundamentally change the human condition, one can easily change the environment in which humans perform.¹⁷ The theoretical basis for this claim comes from Cognitive Psychology and Engineering, most prominently represented in the works on human error by James Reason.¹⁸ He sees human error not as a root cause but a logical consequence of a flawed system. The IOM report cites this analogy by James Reason:

“[U]nsafe acts are like mosquitoes. You can try to swat them one at a time, but there will always be others to take their place. The only effective remedy is to drain the swamps in which they breed. In the case of errors and violations, the “swamps” are equipment designs that promote operator error, bad communications, high workloads, budgetary and commercial pressures, procedures that necessitate their violation in order to get the job done, inadequate organization, missing barriers, and safeguards... the list is potentially long but all of these latent factors are, in theory, detectable and correctable before a mishap occurs.”¹⁹

Thomas Nolan illustrated this concept with an example of everyday-life:²⁰ consider the functionality of an automated teller machine (ATM). The old generation of ATMs released the cash first and then returned the card. This process is reversed in the design of newer ATMs, which will return the card first. The rationale is that less people will forget the card in the machine’s slot. This is a successful example of “engineering

¹⁷ See James Reason, “Human Error: Models and Management” (2000) 320 BMJ 768 at 769; also Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 16 of Appendix 1.

¹⁸ Reason, *Human Error* (Cambridge: Cambridge University Press, 1990); Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate, 1997); Reason, “Human Error: models and management” (2000) 320 BMJ 768-770.

¹⁹ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) at 155.

²⁰ Thomas W. Nolan, “System changes to improve patient safety” (2000) 320 BMJ 771 at 772.

out error” by system design. Often, parallels are drawn to other complex high-risk industries and “high-reliability organisations” such as air traffic control, and the operation of military aircraft carriers and power plants.²¹ Similarly in the context of the healthcare system, so say safety advocates, it must be the aim to systematically engineer out error and engineer in quality. An area of medicine that has already been especially successful in reducing the number of errors in the recent decades is anaesthesiology. Anaesthesiology involves a high level of technology and human-machine interaction, which led the engineer Jeffrey B. Cooper to carry out his human-factors-study in anaesthesiology in 1978.²² He contributed most of the incidents to preventable human errors (82%) but realized at the same time that this was also a matter of perspective. “[A]ll incidents involving disconnections were arbitrarily treated as human error. However since the frequency of such disconnections is a direct consequence of the design of the connectors, these incidents could alternatively be considered equipment failures.”²³ Hence, recurring adverse events can reveal an error-prone design of machines or procedural failures. In other words, failures often occur not because of careless physicians but because skilled physicians act in a systematically deficient workplace. By standardizing and simplifying the procedures and designing machines to be fail-safe, an enormous improvement has been achieved in the safety of anaesthesiology. Identifying frequent and systematic errors offers a great opportunity to prevent them permanently. In healthcare, this idea is applied by standardizing medical equipment and procedures where

²¹ James Reason, “Human Error: Models and Management” (2000) 320 BMJ 768 at 770.

²² Jeffrey B. Cooper, Ronald S. Newbower, Charlene D. Long, Bucknam McPeck, “Preventable Anesthesia Mishaps: A Study of Human Factors” (1978) 49 Anaesthesiology 399-406.

²³ *Ibid* at 401.

appropriate. Furthermore, efforts are undertaken in making medication labels less confusing and switching to unit systems regarding their application.²⁴ This systems approach to medical error, rooted in a rather mechanistic understanding, gained widespread support. The use of “moral free” language – words like “fault” and “blame” are constantly avoided – takes medical errors out of the realm of metaphysical ideas on to a lower level of emotion-free pragmatism and quantification. It makes this view popular among healthcare professionals as well.

C. Critique of the Patient Safety Concept

The systems approach to medical error is challenged conceptually by other approaches. The IOM report has been criticised as single-sided and ignorant to these various other perspectives.²⁵ Cognitive Psychology and Engineering (including Ergonomics) are only two of many disciplines which have developed theories on human fallibility, accidents, and harm. Sociology, Business and Management (“Total Quality Control”), Religion, Ethics and Law all have something to say about the topic, however

²⁴ National Steering Committee on Patient Safety “Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” (2002), available online: <<http://rcpsc.medical.org/publications/>> referring to changes at the Toronto Hospital for Sick Children at 14; Medication errors make a proportionally big part of the errors in the hospital setting. In a survey of 2005/2006 almost one fifth (19%) of Canadian hospital-employed nurses acknowledged that over the previous year, medication error involving patients who were in their care had occurred “occasionally” or “frequently” see Kathryn Wilkins, Margot Shields, “Correlates of medication error in hospitals” (2008) 19 Health Reports 1 at 7. Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) 32-40.

²⁵ Charles Bosk “Continuity and Change in the Study of Medical Error: The Culture of Safety on the Shop Floor” (2005) Unpublished, available online: <www.sss.ias.edu/publications/papers/paper20.pdf>.

each in their own language. Medical error is an elusive concept and the following discussion will outline some approaches to show that.

The law has a variety of responses to medical error and it is hard to grasp all branches of law in all their complexity – Tort Law, Criminal Law, Disciplinary Law, and Labour Law. The patient safety approach does not reflect these multiple dimensions well. The focus of the patient safety approach lies primarily on the prevention of physical injury.²⁶ The law however aims to protect a whole range of interests and values. Consider the doctrine of informed consent: Autonomy and self-determination lie at the core of this doctrine, not solely the physical wellbeing of the patient. Furthermore, patient safety focuses primarily on preventable but not on blameworthy accidents. The reality of malicious acts and recklessness is completely excluded.²⁷ One may fear that the “normalization of error”, as one implication of the systems approach, is a step towards less accountability of individuals and that “blaming the system” itself does not lead to any changes. The new patient safety approach could cause frictions to the law of negligence, which is rooted in the idea of individual responsibility and autonomy. The patient safety approach has very different, far-reaching theoretical implications. The often used phrase “to err is human” suggests that reliance on human performance and individual judgement itself is a major problem. Safety specialists point to fundamental limits of human expertise and to a limited ability to avoid errors individually. James Reason states that human actions are almost always constrained by factors beyond an

²⁶ Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 4 of Appendix 1.

²⁷ *Ibid.* at 5 of Appendix 1.

individual's control,²⁸ and he calls free will "an illusion".²⁹ Indeed, healthcare professionals acknowledge the uncertainty in their work and that their judgement can be erroneous, at least sporadically, sometimes systematically. Today, human judgement is sometimes found to be inferior to new means of diagnosis, some based on computerized information-technology. For example, the expert in coronary care Hans Ohlin, Chief of Coronary Care of Lund Hospital, found in 1996 that a new computer programme was able to interpret the electrocardiogram with 20% more accuracy than himself.³⁰ What will the consequences of findings like these be to the way medicine will be practiced in the future? Industry-like standardization, super-specialization and automation seem to be the remedies of choice to slowly depart from human errors.³¹ The role of the twenty first century-physician may continuously evolve towards being a healthcare operator, being more and more a supervisor and administrator for technologies of diagnosis and treatment. Surely, there are many challenges requiring specific human abilities, and at its core lie traditional abilities such as offering compassion and understanding for the patient. However, there seems to be a growing distrust in individual judgement, even in medicine where highly individualized solutions are necessary.

An example to illustrate the variety of perspectives on medical error is the recent discussion on "disruptive behaviour"³². Examples for disruptive behaviour include the

²⁸ James Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate, 1997) 128.

²⁹ *Ibid.* at 127.

³⁰ Atul Gawande *Complications: A Surgeon's Notes on an Imperfect Science* (New York City: Picador, 2002) at 37.

³¹ See the chapter "The Computer and the Hernia Factory" in Atul Gawande *Complications: A Surgeon's Notes on an Imperfect Science* (New York City: Picador, 2002); also Thomas W. Nolan, "System changes to improve patient safety" (2000) 320 *BMJ* 771 at 772 "Automate wisely".

³² AH Rosenstein, M. O'Daniel, "Disruptive behavior and clinical outcomes: Perceptions of nurses and physicians" (2005) 105 *American Journal of Nursing*, 54-64, see also most recently The Joint Commission,

use of disrespectful, insulting, or demeaning language, inappropriate arguments with patients, family members, staff or care providers and inappropriate rudeness (yelling), outbursts of anger, bullying behaviour, not answering calls, etc.³³ More generally, disruptive behaviour can be defined as the use of inappropriate words, actions or inactions by a physician or nurse or other staff that interferes with his or her ability to work cooperatively.³⁴ Thus, it deals with errors affecting social interaction. For example, a team member may worry because of being yelled at, feeling intimidated and therefore would be unable to concentrate or to communicate openly. The concept of disruptive behaviour is contentious among physicians. Many see it as an instrument of the hospital administration to punish unpopular characters, who may nevertheless deliver excellent healthcare. Some of the most outstanding physicians show exactly these signs of “disruptive behaviour” from time to time. These physicians themselves may not see their behaviour as “disruptive” but rather as strict and appropriate interventions, for example to address carelessness and assuring discipline. Recently, disruptive behaviour has been characterized as an issue of patient safety. The idea is that these forms of behaviour will often distract attention away from the health problems of patients and towards arguments and interaction among healthcare workers themselves. Recent studies show that repeated “disrupted behaviour” can indeed lead to a higher frequency of accidents and compromise patient safety.³⁵ But this is not the only way to look at it considering the connection of disruptive behaviour to social interaction and control. That medical error

Issue 40 of Sentinel Event Alert “Behaviors that undermine a culture of safety”, at <http://www.jointcommission.org/sentinelevents/sentineleventalert/sea_40.htm>.

³³ *Ibid.*

³⁴ *Ibid.*

³⁵ *Ibid.*

has a sociological dimension is not a new idea: Charles Bosk explored the sociological, phenomenological dimension of medical failure in a two-year field study in a surgery unit in 1979.³⁶ He categorized the errors he observed among surgeons as either technical/judgemental errors, or normative errors.³⁷ Normative errors, so found Bosk, are the more serious, sometimes unforgivable mistakes in the understanding of the medical profession. Such errors occur when a physician leaves the boundaries of his role within the group and acts in an unusual or surprising way that his peers would not, or ignores advice and directions.³⁸ The effect of errors on the patient is not crucial in this view but rather the impact of errors on the surrounding professionals. Bosk's observations are important because we can see that error can also be seen as an element of internal struggles of social control and rank. For example, Bosk showed that an attending physician, who practically has no direct superior, can be "immune" to errors, at least in the perception of subordinate residents and interns.

D. Conclusion

Considering these multiple approaches and different understandings, we have to acknowledge the limitations of the patient safety approach. Patient safety advocates show a lot of confidence in establishing their vocabulary despite the existence of these multiple

³⁶ Charles L. Bosk, *Forgive and Remember: Managing Medical Failure* (Chicago and London: The University of Chicago Press, 1979, second edition reprint 2003). and recently: Charles L. Bosk, "Continuity and Change in the Study of Medical Error: The Culture of Safety on the Shop Floor" (2005) Unpublished, available online: <www.sss.ias.edu/publications/papers/paper20.pdf>.

³⁷ Charles L. Bosk, *Forgive and Remember: Managing Medical Failure* (Chicago and London: The University of Chicago Press, 1979, second edition reprint 2003) at 35-70.

³⁸ *Ibid.* at 51.

other approaches, concepts, and categorizations. The patient safety approach has great value for systematic improvements. However, medical error is an elusive concept. In part, it is fair to say that the patient safety approach is sometimes “overblown rhetoric”³⁹. Furthermore, we can say that the goal of the IOM’s report to cut the number of errors in half within 5 years⁴⁰ was an illusion, in part because of the lack of a reliable baseline, but in part also conceptually because of the many other approaches to medical error.⁴¹

III. The Tort System and the Search for New Solutions

The following part starts with a discussion of the persisting critique of tort-based medical malpractice litigation in Canada. However, I will also highlight two promising developments within the tort system. The first aspect is the disclosure of medical error to patients. The second is the increased use of class actions to address systemic errors and to hold healthcare managers accountable for unsafe conditions. The tort system has in common with other legal procedures that it reacts too late when patients are already injured. The paper concludes that the emerging reporting systems may address unsafe conditions more proactively.

³⁹ Carol Brayshaw Longwell “Pennsylvania’s Patient Safety Authority: Another Perspective” (2005) 63 *Pennsylvania Bar Association Quarterly* 63 at 72.

⁴⁰ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) 4.

⁴¹ Sceptical also Maxine M. Harrington, “Revisiting Medical Error: Five Years after the IOM Report, Have Reporting Systems made a Measurable Difference?” (2005) 15 *Health Matrix* 329-382 at 381 “Reducing medical error by a precise figure is a goal that cannot easily be attained because many errors cannot be measured with any degree of accuracy.”

A. Critique of the Tort System

Critique of tort-system in medical malpractice has a long tradition. Usually, critics claim that the law of medical malpractice does not fulfill its purposes: it would neither compensate harmed patients efficiently nor have a sufficient deterrent effect on negligent physicians.⁴² Also, the administrative costs of the system (fees for lawyers etc.) are too high with respect to the achieved level of compensation. Even worse, the tort system has been found to have a number of unwanted side-effects. The adversarial nature of the process is responsible for a “culture of secrecy” surrounding medical errors. The Canadian National Steering Committee on Patient Safety found: “[T]he current legal and regulatory environment in health care perpetuates fear of blame and litigation. As a result, disclosure discussions and quality improvement processes may not involve an open dialogue and sharing of questions or concerns.”⁴³ In addition, some evidence for “defensive medicine” has been found in Canada.⁴⁴ Defensive medicine is mostly a phenomenon the United States as part of the malpractice crisis. It means that the fear of lawsuits leads to over-deterrence, altering the practice of medicine towards excessive or medically unnecessary diagnosis and treatment in order to prevent lawsuits or even discouraging some physicians to practise in high risk areas of medical practice.⁴⁵

⁴² Don Dewees, David Duff, Michael Trebilcock, *Exploring the Domain of Accident Law – Taking the Facts Seriously* (Oxford: Oxford University Press, 1996) at 112 “Summary” for deterrence, and at 117 for compensation.

⁴³ National Steering Committee on Patient Safety “Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” (2002), available online: <<http://rcpsc.medical.org/publications/>> at 12.

⁴⁴ Ellen I. Picard, Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada 4th Edition* (Toronto: Thomson Carswell, 2007) 13 (1) (b) (iv).

⁴⁵ *Ibid.*

Canadian patients are rarely compensated by the tort-system. In 1990, the Prichard Report estimated that the tort system leads to compensation only in less than 10 percent of potential viable claims.⁴⁶ The Canadian Medical Protective Association (CMPA), of which almost all Canadian physicians are members, provides comprehensive statistical information on malpractice lawsuits in Canada on an annual basis. In its 2007 report, the CMPA states that the number of legal actions per thousand members has gradually declined over the past ten years.⁴⁷ For a physician in Canada today, it is nearly half as likely to be involved in a legal action as it was 10 years ago.⁴⁸ One common assertion is that universal healthcare coverage in Canada may be a crucial disincentive for harmed patients to commence lawsuits because further treatment (in case of healthcare-induced injury) is universally provided. A patient will undergo treatment as long as medically necessary, not as long as he or she can afford it. However, the decline in the recent years cannot be attributed only to universal healthcare anymore. It could be a sign that disputes are being solved in different ways or a sign of increased risk management. It might also be an indicator for a growing imbalance in judicial protection between physicians and patients.

Despite their strong legal protection, physicians often perceive the law of tort as an enormous threat. It is seen as an instrument to punish hard-working professionals unfairly. Legal procedures can create fear, anxiety and stress in the minds of physicians and nurses. If these effects would merely lead to higher caution and vigilance, it would

⁴⁶ J. Robert S. Prichard, (Chairman) "Liability and Compensation in Health Care – A Report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care" (Toronto: University of Toronto Press, 1990) 17.

⁴⁷ The Canadian Medical Protective Association (CMPA), "2007 CMPA Annual Report" (2008) available online: <<http://www.cmpa-acpm.ca>> at 7.

⁴⁸ *Ibid.*

foster the safety goal. But a lawsuit often leads to anger and self-doubts. A malpractice lawsuit can be emotionally damaging for both sides because of the adversarial nature of the procedure.⁴⁹ Once a legal process commences, adversity and vengeance often form the mindset of the parties and create a hostile and destructive setting. The Journal of the Canadian Medical Association cited a Canadian doctor on his experience with a malpractice lawsuit:

“[I]’d rather not talk about it, even though in the end no fault was found. For 7 years it went on, months sitting in court listening to what a terrible person you are, no one recovers from that. It is on your mind every day, every minute. It changed the whole way I practised. The empathy I had, that I was known for, just wasn’t there any more. Every patient was a potential lawsuit.”⁵⁰

The physician-patient relationship, which is built on trust, comes to a definitive end. In addition, there can be a feeling that when lawyers take over a case and impose their legal vocabulary, they distort the original understanding that the healthcare professionals and patients had of their case.⁵¹ When lawyers shift the focus towards legal thresholds, plaintiffs and defendants find their communication restricted to legally relevant aspects. For the parties, this can create frustration, a feeling of helplessness, and the impression that justice is an exclusive domain of legal professionals.⁵²

⁴⁹ Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 26.

⁵⁰ Ann Silversides, “Fault/no fault: bearing the brunt of medical mishaps” (2008) 179 CMAJ 309.

⁵¹ Sydney Dekker, *Just Culture: Balancing Safety and Accountability* (Aldershot: Ashgate Publishing Limited, 2007) prologue, 1-16.

⁵² *Ibid.*

The tort-system often serves as the focal point of the discussion,⁵³ despite not being the only legal mechanism that addresses medical error: Disciplinary proceedings can also be commenced to assure the integrity of the medical profession and to protect the public. Sanctions in labour law can assure accountability too. In outrageous cases, the criminal law can even step in. However, the tort system takes the centre stage and reform projects usually focus on it. Alternatives to the entire tort-system have frequently been discussed in the last decades: Most notably, administrative compensation and insurance schemes have been successfully established in New Zealand, Finland, and Sweden. This type of scheme was also proposed in Canada in 1990 (Prichard Report),⁵⁴ but has not been realized.⁵⁵ Also, a strict hospital liability could improve the situation.⁵⁶ Alternative Dispute Resolution (ADR) and new complaints-mechanisms are increasingly identified as promising approaches. Within the tort-system itself, there have also been some promising developments to identify systemic deficiencies. Liability for non-disclosure of medical error, and the increasing use of class actions aim towards the safety goal.

⁵³ See for the United States: Robert B Leflar, Futoshi Iwata, "Regulating for Patient Safety: The Law's Response to Medical Errors: Medical Errors as Reportable Event, as Tort, as Crime: A Transpacific Comparison" (2005) 12 *Widener L. Rev.* 189 at 191 "In American jurisprudence, it is tort law – specifically, medical malpractice law – that casts the longest shadow over controversies relating to medical injuries. Whether the topic is avoiding defensive medicine, encouraging self-critical analysis for the purpose of quality improvement, ensuring the availability of high (legal) risk medical services, or protecting the rights of the injured, all eyes turn first to tort."

⁵⁴ J. Robert S. Prichard, (Chairman) "Liability and Compensation in Health Care – A Report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care" (Toronto: University of Toronto Press, 1990).

⁵⁵ See recently Ann Silversides "Fault/no fault: bearing the brunt of medical mishaps" (2008) 179 *CMAJ* 309-311.

⁵⁶ See for instance, Bruce Chapman "Controlling the costs of medical malpractice: An argument for strict hospital liability" (1990) 28 *Osgoode L.J.*

B. Developments within the Tort System to foster Patient Safety

Almost a decade after the patient safety movement started, one can say that the focus on medical error and safety has increased the mechanism of accountability despite an emphasis on systematic improvements. Liability may now shift increasingly to those individuals, such as healthcare and risk managers that can influence and improve unsafe conditions. There are two aspects emerging in the current tort-system that I will highlight. One is the debate around disclosure of errors to patients and the public, and the other is the use of class actions in cases of systemic negligence. Persisting barriers show that open disclosure can only be a serious answer to overcome the culture of secrecy upon the condition that legislature undertakes changes. Either, legal sanctions of non-disclosure have to be so severe that the risk of discovery is not worth any attempts of concealment, or the adversary system with respect to compensation has to change to an administrative insurance solution that also eases the patient-physician-relationship. The second development that I like to highlight is the increased use of class actions in Canada. Class actions provide a great opportunity to shed light on systemic errors and foster patient safety.

1. Disclosure of Error and Apology to Patients and the Public

Informed changes require knowledge about unsafe conditions that lead to mistakes. A precondition to achieve this goal is to circumvent the “culture of secrecy” that surrounds medical errors. Safety advocates argue for both the disclosure of errors to

patients (at least if the patient was harmed) and reporting of adverse events (including near misses) to a reporting system. Certainly, the rationales for disclosure and confidential reporting differ. Disclosing an error to the patient is essential for the individual patient and the relation to the physician or nurse. Ethically, it means that the healthcare professional can show responsibility, integrity, honesty and truthfulness. Disclosure may also be required to establish informed consent, when subsequent treatment becomes necessary because of the error. In contrast, the individual patient does not directly benefit from reporting an error to a reporting system. But, the two issues are also intrinsically tied. It would be much easier if healthcare professionals would actually disclose all errors to the patient and the public. Complex provisions to protect the confidentiality of reporters would become unnecessary.

Under common law, a physician has a duty to disclose errors to the patient.⁵⁷ Already in 2007, 11 of the 27 reporting systems in the U.S. required physicians to also disclose errors to the patients.⁵⁸ In addition, there has been an enormous increase in soft-law on the topic. The Council of the Ontario College of Physicians and Surgeons (CPSO) has developed a policy titled “Disclosure of Harm”.⁵⁹ Furthermore, in March 2008, the Canadian Patient Safety Institute released the Canadian Disclosure Guidelines.⁶⁰ The

⁵⁷ *Stamos v. Davies*, (1985), 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 (H.C.); *Kueper v. McMullin*, (1986), 30 D.L.R. (4th) 408, 37 C.C.L.T. 318 (N.B.C.A.); *Vasdani v. Sehmi*, [1993] O.J. No. 44, 37 A.C.W.S. (3d) 856; *Gerula v. Flores*, (1995), 126 D.L.R. (4th) 506 [1995] O.J. No. 2300; *Fehr v. Immaculata Hospital*, [1999] A.J. No. 1317, 1999 ABQB 865; see Michael Allen Waite, *Patient Safety & Disclosure of Medical Error: The Legal & Ethical Implications of Human Error in Medicine*, Master-Thesis Edmonton, University of Alberta 2006, 38-67.

⁵⁸ NASHP 2007 Guide to State Adverse Event Reporting Systems, online at http://www.nashp.org/_docdisp_page.cfm?LID=B20C4AF8-3BFF-43EA-A02A83A4D15BB06E.

⁵⁹ <<http://www.cpso.on.ca/Policies/disclosure.htm>>.

⁶⁰ Canadian Patient Safety Institute, *Canadian Disclosure Guidelines*, (March 2008), available online at <<http://www.patientsafetyinstitute.ca/Disclosure.html>>.

guidelines are intended to encourage healthcare providers in developing and implementing disclosure policies, practices and training methods.⁶¹ Their basic conclusion is that disclosure is always the right thing to do, echoing the dominant rhetoric of open disclosure in the current literature. But disclosure of medical error to patients remains highly problematic. Unfortunately, there are various barriers to disclose errors to patients or the public. The following discussion highlights some of the persisting problems of disclosure in an adversarial system and under the current circumstances.

One of the challenges of the disclosure debate is to achieve clarity of what the consequences of disclosure and non-disclosure are. On an emotional level, we know that non-disclosure, “bunker mentality” and the “wall of silence” can lead to anger and frustration.⁶² Studies from the United States suggest that a policy of open disclosure in hospitals does actually not lead to more lawsuits but less.⁶³ In addition, open disclosure encourages settlements with sums that are lower than those in lawsuits.⁶⁴ However, this is a broader economic perspective that is interesting for policy makers and the legislature, but not for the individual physician. The considerations and legal advice on an individual level would currently be quite different. What are currently the legal consequences and sanctions of non-disclosure that would represent real incentives for disclosure? Once an

⁶¹ *Ibid.* At 9.

⁶² Catherine A.G. Sparkman, “Legislating apology in the context of medical mistakes” (2005) 82 AORN Journal (Journal of the Association of periOperative Registered Nurses) 263-272 at 263.

⁶³ Bhavani S. Reddy, “Apology and Medical Error Full Disclosure Programs: Is Saying “I’m Sorry” the Answer to Reducing Hospital Legal Costs?” (2006) Health Law Perspectives (Houston), only available online at: <[www.law.uh.edu/healthlaw/perspectives/2006%5C\(BR\)ApologiesFinal.pdf](http://www.law.uh.edu/healthlaw/perspectives/2006%5C(BR)ApologiesFinal.pdf)>; Michael Nowicki, “Do healthcare managers have an ethical duty to admit mistakes?” (1998) 52 Healthcare Financial Management 62.

⁶⁴ Jennifer K. Robbennolt, “Apologies and Legal Settlement: An Empirical Examination” (2003) 102 Michigan Law Review 460-516.

error has happened, the damage is usually fully unfolded. Only in rare cases, the non-disclosure causes additional physical damage to the health of the patient, for example if subsequent treatment is delayed. Nevertheless, the courts have found certain legal consequences. In some outrageous cases, punitive damages were awarded and in other cases, concealment of errors may lead to an extension of limitation periods.⁶⁵ As the following examples will show, there is little consistency. *Stamos v. Davies* (1985)⁶⁶ was the first case that established the duty to disclose medical errors in the Canadian law of negligence. However, no additional liability arose from the failure to disclose a surgical mishap because it did not cause further harm. In *Kueper v. McMullin*, (1986)⁶⁷, a dental surgeon failed to inform the patient that a drill broke off in a tooth during root-canal surgery. Again, no liability arose from the failure to disclose the error. Also, the court held the patient would have agreed to the treatment that was commenced by the physician subsequently even if he was informed about the error properly. In *Gerula v. Flores* (1995)⁶⁸, a surgeon performed a spine surgery at the wrong disc level (L4-5 instead of L3-4). A follow-up CAT scan revealed the mistake, but the surgeon did not inform his patient about it. Instead, he altered the medical records. In this case of deliberate non-disclosure, the patient was awarded \$ 40,000 in punitive damages. In *Vasdani v. Sehmi* (1993)⁶⁹ another surgeon performed a spine surgery at the wrong disc level (in this case on the L3-4 level instead of L4-5). He learned about his mistake about one year later. The judge decided that the surgeon still had the obligation to disclose the

⁶⁵ Instructive Ellen I. Picard, Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada* 4th Edition (Toronto: Thomson Carswell, 2007) 205.

⁶⁶ *Stamos v. Davies*, (1985), 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 (H.C.).

⁶⁷ *Kueper v. McMullin*, (1986), 30 D.L.R. (4th) 408, 37 C.C.L.T. 318 (N.B.C.A.).

⁶⁸ *Gerula v. Flores*, (1995), 126 D.L.R. (4th) 506 [1995] O.J. No. 2300.

⁶⁹ *Vasdani v. Sehmi*, [1993] O.J. No. 44, 37 A.C.W.S. (3d) 856.

error to the patient, even though the patient was not in his care anymore. The patient was awarded pre-trial interest on the damages because of the delay of knowledge about the mistake from the moment the surgeon knew about it. One can see from these cases that the legal consequences are inconsistent and insufficient. Physicians today still have many incentives to conceal an error when we compare it to the possible consequences. If the physician does not disclose, the case might never be discovered and there may be no legal sanctions and negative effects including any diminishing of reputation. If the error is discovered and the patient actually claims damages, the legal consequences seem very similar to those that would occur if he had disclosed the occurrences right from the start. Additional sanctions for non-disclosure are not severe enough. They add only little to the many worries that the physician might possibly face in any case.

Furthermore, many professional liability insurance policies include a “non-admission of liability clause” or “cooperation clause”.⁷⁰ The insured physician is not allowed to admit his liability or initiate a settlement agreement on his own. If the physician does, he or she may lose the insurance coverage. The Canadian Disclosure Guidelines stress the importance of giving the patient merely “the facts” and avoid the

⁷⁰ Lee Taft “Disclosure Danger: The Overlooked Case of the Cooperation Clause” (2007) 8 Harvard Health Policy Review 150-157; Digby Charles Jess, *A Guide to the Insurance of Professional Negligence Risks* (London: Butterworths 1982) at 205; British Columbia, Ministry of Attorney General, *Discussion Paper on Apology Legislation*, January 30, 2006, available online at: <www.ag.gov.bc.ca/dro/publications/other/Discussion_Apology_Legislation.pdf> at page 6; Public Legal Association of Saskatchewan (PLEA), *Apologies and the Law*, March 9, 2007, available online at: <<http://www.plea.org/freepubs/newspaper/apology.htm>>; similarly under German Law, compare Michael Terbille, Stephan Schmitz-Herscheidt, “Zur Offenbarungspflicht bei ärztlichen Behandlungsfehlern” (2000) (engl.: On the Duty to Disclose Medical Errors) NJW 2000, 1749-1756 at 1756; and especially Michael Kleuser, *Die Fehleroffenbarungspflicht des Arztes – unter besonderer Berücksichtigung der versicherungsrechtlichen Obliegenheiten nach einem Behandlungszwischenfall* (engl.: The Physician’s Duty to Disclose Errors – in Particular with Respect to the Obligations of Insurance Law after Medical Incidents) (Karlsruhe: Verlag Versicherungswirtschaft e.V. 1995).

use of words like “error” and “mistake” and “fault”.⁷¹ Although, the facts may be enough if the conclusion is arrived at easily as in cases of severe medication errors or wrong-side surgery. The physician needs full support of the insurance company before disclosing errors. If physicians are asked to handle errors more proactively, then the compensation issue has to be clear and addressed more proactively as well. Currently, this runs contrary to the financial interests of the insurance companies and physicians paying the premiums. To change the law at this point means to transform the malpractice insurance substantially. It is a broad policy decision that brings back the idea of a no-fault compensation scheme. It also shows that there is a direct normative link between disclosure and compensation.⁷²

However, some argue that compensation is not always the most important motivation for patients to sue their doctors. Victims of medical mistakes will often only seek to find answers to what exactly happened (“the truth”), while compensation and legal sanctions remain secondary objectives. A survey, published in the journal *The Lancet* in 1994 showed that “compensation” was only one of four important motivations for U.S. patients suing doctors along with the wish for “accountability”, “getting an explanation”, and “improving the standard of care to prevent similar incidents”.⁷³ However, one has to point to the limitations of the study that claimed that compensation was often only secondary motivation when suing physicians. The editors of *The Lancet* themselves warned of putting too much reliance on the findings especially considering

⁷¹ Canadian Disclosure Guidelines, *supra* note 60 at 11.

⁷² Lee Taft “Within A Moral Dialectic: A Reply To Professor Robbennolt” (2005) 103 Michigan Law Review 1010-1017.

⁷³ Charles Vincent, Magi Young, Angela Phillips, “Why do people sue doctors? A study of patients and relatives taking legal action” (1994) 343 *The Lancet* 1609-1613.

the methodology of a postal questionnaire after the litigation has already ended.⁷⁴ Still, disclosure itself and also an “expressions of regret” (apology) are of great value and should be encouraged,⁷⁵ but the question remains how to realize this goal legally. In the United States, about 20 states, and recently also the Canadian province of British Columbia⁷⁶ have enacted “apology laws”.⁷⁷ These acts usually amend the rules of evidence and ensure that “expressions of empathy, compassion and regret (apologies)” are not admissible as evidence and that these expressions are never interpreted as “admissions of liability” in civil proceedings. The rationale is to encourage honesty and apologies for their beneficial effects and healing capacity.⁷⁸ However, as it has been pointed out by Lee Taft, these laws are normatively flawed.⁷⁹ In cases where compensation is actually required, the physician can theoretically make an apology but refuse to pay compensation at the same time.⁸⁰ Subsequently, the physician may also win in court if the harmed patient is not able to prove negligence in a different way.⁸¹ These

⁷⁴ The Lancet Editorial “Suing the doctor: altruism, naked truth, or recompense?” (1994) 343 The Lancet 1582-1583 “People who complete such reports may give answers that they think are desirable but that are not necessarily correct.”

⁷⁵ Canadian Disclosure Guidelines, *supra* note 60 at 23.

⁷⁶ British Columbia, Ministry of Attorney General, *Discussion Paper on Apology Legislation*, January 30, 2006, available online at: www.ag.gov.bc.ca/dro/publications/other/Discussion_Apology_Legislation.pdf.

⁷⁷ See a list of the current states that have apology laws at: The *Sorry Works!* Coalition, “States with Apology Laws” available online at: <http://www.sorryworks.net/lawdoc.phtml>, a good overview is also provided by Catherine A.G. Sparkman, “Legislating apology in the context of medical mistakes” (2005) 82 AORN Journal (Journal of the Association of periOperative Registered Nurses) 263 at 269-271; see also Marlynn Wei, “Doctors, Apologies, and the Law: An Analysis and Critique of Apology Laws” (2007) - working paper, available online at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=955668 at 3.

⁷⁸ Catherine A.G. Sparkman, “Legislating apology in the context of medical mistakes” (2005) 82 AORN Journal (Journal of the Association of periOperative Registered Nurses) 263-272 at 263.

⁷⁹ Taft, *supra* note 72 at 1010-1017.

⁸⁰ Taft, *supra* note 72 at 1015 and Public Legal Association of Saskatchewan (PLEA), Apologies and the Law, March 9, 2007, available online at: <http://www.plea.org/freepubs/newspaper/apology.htm>.

⁸¹ Taft, *supra* note 72 at 1015 “[...] the result is horrific.”

laws encourage strategic, insincere and “partial apologies”.⁸² Disclosure and apology cannot avoid liability where it is necessary.⁸³ Lee Taft described this as the mistake of the legislature trying to transplant parts of moral concepts (apology) into a primarily adversarial system.⁸⁴ Even the current presidential candidate Barack Obama has endorsed the so called “The *Sorry Works!*-Coalition”, which supports the new apology laws.⁸⁵ The idea that saying sorry “works” or is “effective” is a bizarre understanding of responsibility.⁸⁶ Apologies that are motivated by legislative protections are not upright. The law must not “distort the moral compass”⁸⁷ by fragmenting behaviour this way.

A legal duty of disclosure also finds limitations in the right against self-incrimination. This aspect is more important in countries where the criminal law is more frequently used in the area of medical malpractice, for example in the countries of continental Europe⁸⁸ and Japan⁸⁹. But a Canadian physician may face disciplinary proceedings after a mistake, which can have severe consequences equal to punishments in many aspects. Does the right against self-incrimination apply in these cases and trump

⁸² Taft, *supra* note 72 at 1016 and Public Legal Association of Saskatchewan (PLEA), Apologies and the Law, March 9, 2007, available online at: <<http://www.plea.org/freepubs/newspaper/apology.htm>>.

⁸³ Bhavani S. Reddy, “Apology and Medical Error Full Disclosure Programs: Is Saying “I’m Sorry” the Answer to Reducing Hospital Legal Costs?” (2006) Health Law Perspectives (Houston), only available online at: <[www.law.uh.edu/healthlaw/perspectives/2006%5C\(BR\)ApologiesFinal.pdf](http://www.law.uh.edu/healthlaw/perspectives/2006%5C(BR)ApologiesFinal.pdf)>.

⁸⁴ Taft, *supra* note 72 at 1016.

⁸⁵ Ken Braxton, Kip Poe, “Disclosure of Medical Errors – Is Honesty The Best Policy Legally?” (2006) 2 American Bar Association Health eSource, available online at: <<http://www.abanet.org/health/esource/vol2no5/braxton.html>>.

⁸⁶ See also Taft, *supra* note 72 at 1016.

⁸⁷ Taft, *supra* note 72 at 1016.

⁸⁸ For Germany: Jochen Taupitz, *Die zivilrechtliche Pflicht zur unaufgeforderten Offenbarung eigenen Fehlverhaltens* (engl.: The Civil Law Duty to Disclose One Own’s Errors Unrequested”) (Tübingen: Mohr Siebeck 1989) at 102 at 30; and Michael Terbille, Stephan Schmitz-Herscheidt, “Zur Offenbarungspflicht bei ärztlichen Behandlungsfehlern” (2000) (engl.: On the Duty to Disclose Medical Errors) NJW 2000, 1749-1756 at 1751.

⁸⁹ Robert B. Leflar, Futoshi Iwata “Regulating for Patient Safety: The Law’s Response to Medical Errors: Medical Errors as Reportable Event, as Tort, as Crime: A Transpacific Comparison” (2005) 12 Widener L. Rev. 189-225.

the duty of disclosure? Is there a right to remain silent after a mistake happens, depending on its severity or the state of mind of the physician? It seems at least counter-intuitive that we ask physicians to give up their defensive attitude⁹⁰ and surrender all self-interests. To establish a duty of disclosure is a severe, normative shift. “[T]his type of duty to disclose is by no means the norm. As a general rule, Canadian law does not require confession – potential defendants are entitled to remain silent, at least until they are sued and the discovery process begins.”⁹¹

These persisting barriers show that the duty of disclosure needs to be strengthened by the legislature in a comprehensive reform. Either, legal sanctions of non-disclosure have to be so severe that the risk of discovery is not worth any attempts of concealment, or the adversary system with respect to compensation has to change to an administrative insurance solution that also eases the patient-physician-relationship. In no-fault compensation schemes, accidents can more easily be disclosed and the data may also be used for safety improvements.

⁹⁰ *Contra* Philip C. Herbert, Alex V. Levin, Gerald Robertson, “Bioethics for clinicians: 23. Disclosure of medical error” (2001) 164 CMAJ 509-513 available online at: <<http://www.cmaj.ca/cgi/content/full/164/4/509>> at 512 “They [physicians] should try not to act defensively [...]”.

⁹¹ Gerald B. Robertson, “When Things Go Wrong: The Duty to Disclose Medical Error” (2002) 28 Queen’s Law Journal 353-362 at 357.

2. Class Actions to address Systemic Errors

The discovery of systematic misdiagnosis at Miramichi's pathology laboratory in New Brunswick (2008)⁹² and cases such as *Rideout v. Health Labrador Corp* (2005)⁹³ *Bellaire v. Daya* (2007) in Ontario⁹⁴ draw attention to the successful use of class actions in the context of medical malpractice and patient safety. Numerous successful certifications in Canada show that class actions can be a powerful tool for patients to address instances of systemic negligence. Class actions provide an example of how liability shifts towards healthcare and safety managers. In addition, class actions receive national media coverage⁹⁵ and thereby increase awareness for patient safety.

Certification is a crucial stage of class action proceedings. The challenges that arise in cases of medical negligence can be exemplified at the Ontario Class Proceedings Act (CPA): Class counsel has to show that the claims raise "common issues" according to s. 5 (1) (c) CPA. One might think that this requirement would be most difficult to meet because cases of medical negligence usually raise questions of causation⁹⁶ and informed consent on a highly individual level. Therefore, one might assume that cases of medical negligence are not suited for class actions at all. Judges might instinctively switch to the

⁹² Wagners Law Firm "Miramichi (Pathology) Class Action – A Case Summary", available online <<http://miramichiclassaction.com/miramichi/>>.

⁹³ *Rideout v. Health Labrador Corp.* (2005) 12 C.P.C. (6th) 91 (certification); (2007), 270 Nfld. & P.E.I.R. 90.

⁹⁴ *Bellaire v. Daya* (2007) 49 C.P.C. (6th) 110.

⁹⁵ CBC News, "Eastern Health can't win breast cancer lawsuit: premier" April 14, 2008, available online: <<http://www.cbc.ca/canada/newfoundland-labrador/story/2008/04/14/missing-patients.html>>; CBC News, "Lawyers prepare class action for Miramichi patients" February 15, 2008, available online: <<http://www.cbc.ca/health/story/2008/02/15/miramichi-lawsuit.html>>.

⁹⁶ A fascinating analysis of the topic of causation in medical liability is Lara Khoury's *Uncertain Causation in Medical Liability* (Cowansville: Les Éditions Yvon Blais Inc., 2006).

consideration that individual trials might be the “preferable procedure” according to s. 5 (1) (d) CPA. However, “common issues” is defined in s. 1 CPA as common issues of fact or common issues of law. McLachlin C.J. stated that the purpose of this requirement is to find out whether allowing the suit will “avoid duplication of fact-finding or legal analysis”.⁹⁷ Thus, an issue will be common if its resolution is necessary to the resolution of each class member’s claim. It is not required that the class members are identically situated or that common issues predominate over non-common issues.⁹⁸ Each class member’s claims must share “a substantial common ingredient” to justify a class action.⁹⁹ It is sufficient if all members of the class would benefit from the class action to some extent by bringing the litigation forward. There are numerous cases of “systemic negligence” that show how class action can be used to address deficiencies in patient safety. Systemic negligence in medical law means that the applied level of care sinks systematically below of what is required by the standard of care. Systemic negligence can also occur when an obsolete or outdated medical method of treatment is constantly used despite a progress in medicine prescribing a different, improved method. Systemic negligence also occurs when hygienic precautions are not kept or sanitary regulations are not strictly followed. These are exactly some of the unsafe conditions and recurring errors that the patient safety movement likes to address because they harm a large number of patients systematically. Most class actions in the area of medical negligence involve hygienic failures (often the failure to properly sterilise medical instruments) as

⁹⁷ *Western Canadian Shopping Centres Inc. v. Dutton* [2001] 2 S.C.R. 534 at para 39.

⁹⁸ *Ibid.*

⁹⁹ *Ibid.*

the following examples illustrate. In *Anderson v. Wilson*¹⁰⁰, the defendant Dr. Wilson operated five clinics that provided electroencephalogram tests (EEGs, measurement of the electrical activity of the brain) between 1989 and 1996. A public health inspector identified a possible link between the defendant's clinic and an outbreak of Hepatitis B. Public Health Authorities notified over 18,000 patients that they may have been infected and that they should be tested. At least 75 patients are known to have contracted the illness and 3 had to be hospitalized. Furthermore, these infections put the lives of the partners, children and friends, who may have contracted the infections subsequently, at risk. In *Rideout v. Health Labrador Corp.* (2005), the plaintiff patient claimed that the defendant had failed to properly sterilize medical instruments at a gynaecological clinic. The defendant was the hospital board which had been responsible for the management, control and operation of a hospital in Labrador City. Between October 2001 and March 2003, 333 women were put at risk of infections such as Hepatitis B, Hepatitis C, HIV, Chlamydia, and Gonorrhoea. The case was discovered because the defendant himself had issued a press release stating that unsterile instruments had been used. A similar case involving hygienic failures is *Rose v. Pettie* (2004)¹⁰¹. The class members had received acupuncture treatment from the defendant between January 2000 and December 2002. The defendant had reused needles and had not sterilised the needles between treatments. The plaintiff alleged that he should have used single-use disposable and pre-sterilised needles. Some patients contracted skin infections (*Mycobacterium abscessus*), HIV,

¹⁰⁰ *Anderson v. Wilson* (1999), 175 D.L.R. (4th) 409, 44 (EEGs and Infections).

¹⁰¹ *Rose v. Pettie* (2004), 43 C.P.C. (5th) 183.

Hepatitis B and Hepatitis C. In *Scott v. St. Boniface General Hospital* (2002)¹⁰², certain patients undergoing tests in the Gastroenterology Laboratory of St. Boniface General Hospital between May 1992 and April 1999 were infected with Hepatitis B, Hepatitis C and HIV. Two reusable tubes were not disinfected properly. The hospital contacted 1,959 former patients. Three of them were tested positive for Hepatitis C. Similarly in Alberta, a statement of claim and motion for class action has been brought forward by patients who probably contracted HIV and Hepatitis while undergoing different procedures (tonsillectomy, wound care, dental restorations, vasectomy, internal scoping procedures, and hernia repair) in a hospital.¹⁰³

In addition to these cases involving hygienic failures, we can also see a number of products liability cases that address frequently occurring adverse events in healthcare. Those cases involve unsafe drugs (Vioxx etc.), unsafe mechanical heart valves coated with Silzone¹⁰⁴, defective breast implants, and a cleaning solution for contact lenses causing eye irritations and blindness in certain cases¹⁰⁵. Cases that lie somewhat between products liability and medical negligence are those of patients receiving contaminated blood transfusions¹⁰⁶ or human tissue transplants. In *Birrell v. Providence Health Care*

¹⁰² *Scott v. St. Boniface General Hospital* (2002) 165 Man. R. (2d) 181.

¹⁰³ *Mihalcheon v. East Central Health owning and operating a hospital known as St. Joseph's General Hospital* (July 26, 2007), available online on the National Class Action Database:

<http://www.cba.org/ClassActions/class_2007/alberta/main/2007-07-26_stjosephs.aspx>.

¹⁰⁴ *Andersen v. St. Jude Medical Inc.* (2003) 38 C.P.C. (5th) 122.

¹⁰⁵ See the most recent statement of claim following those in other provinces of *Sophie Lavoie v. Advanced Medical Optics Inc., and AMO Canada Company* (April 8, 2008) on the National Class Action Database, available online: <http://www.cba.org/ClassActions/Class_2008/quebec/main/2008-08-04_Lavoie.aspx>.

¹⁰⁶ *Parsons v. Canadian Red Cross Society* (1999) 40 C.P.C. (4th) 151 (1st Settlement Approval: Contamination of Canadian blood supply with infectious viruses during 1986-1990); *McCarthy v. Canadian Red Cross Society* (2001) 8 C.P.C. (5th) 341 (2nd Settlement Approval: Contamination of Canadian blood supply with infectious viruses before 1986 and after 1990).

Society (2006), patients were at risk of infections after receiving tissue transplants from an “ear bank” because of incomplete and insufficient records regarding the tissue donors.

A good case for illustrating systemic negligence with respect to out-dated methods of medical care is *Bellaire v. Daya* (2007).¹⁰⁷ The defendant was an obstetrician and gynaecologist who treated fertility problems and recurrent pregnancy loss with a type of surgery called “Tompkins Metroplasty” from January 1990 to March 2004. This type of surgery is designed to correct an abnormality in the internal shape of the uterus in order to decrease the risk of pregnancy loss. However, this method is highly invasive and the mother can subsequently give birth to a child only with a Caesarean cut. Progress in the medical sciences had replaced this type of surgery during the 1990s with a less invasive approach, which then began to represent the standard of care. Despite the new developments, the gynaecologist still performed Tompkins Metroplasty on 93 patients. In Australia, a similar case of a gynaecologist performing inaccurate surgeries (and also assaulting his patients) became known as the so called “Butcher of Bega”, and will lead to a class action of harmed patients.¹⁰⁸ Several cases in the more recent time involve false diagnosis after erroneous biopsies were performed by pathology laboratories. For example in Newfoundland and Labrador, at least 300 breast cancer tests between 1997 and 2005 were not conducted properly and negative results were reported despite cancerous tissue samples.¹⁰⁹ Only in one class action regarding medical negligence,

¹⁰⁷ *Bellaire v. Daya* (2007) 49 C.P.C. (6th) 110.

¹⁰⁸ Kathy Sharpe, “Calls for class action against Butcher of Bega” *The Advocate* (Australian Newspaper) February 25, 2008, available online: <http://nwtasmania.yourguide.com.au/articles/1189835.html>.

¹⁰⁹ CBC News, “Eastern Health can’t win breast cancer lawsuit: premier” April 14, 2008, available online: <http://www.cbc.ca/canada/newfoundland-labrador/story/2008/04/14/missing-patients.html>.

Egglestone v. Barker [2003]¹¹⁰, certification failed because “informed consent” was falsely seen as a predominant individual issue. The plaintiffs were patients at the Penetanguishene Mental Health Centre. They resided in a maximum security psychiatric division known as Oak Ridge. Oak Ridge was a facility in Ontario for the custody and treatment of the dangerous, or unmanageable, mentally ill, also referred to as “criminally insane”. Drs Barker and Maier, who were employed at the facility between 1965 and 1979, performed experimental treatments on the patients including techniques such as solitary confinement, sensory deprivation, humiliation, force, restraints, and the use of hallucinogens and delirium-producing drugs. The judge denied certification because he saw the question of whether consent to participate in the program was required and would be a defence as “fundamental and central” to each individual case.¹¹¹ I cannot agree with this reasoning. Instead of highlighting the individual dimension of consent (as a defence to battery and breach of fiduciary duty), I would emphasize the coercive environment and the experimental nature of the systematically flawed treatment program. Both aspects provide sufficient common issues to commence a class action to determine whether there was a form of systemic negligence.

One can conclude from the numerous successful certifications in Canada that class actions can be a powerful tool for patients to address instances of systemic negligence. Individual issues of causation and consent do not necessarily hinder certification. Furthermore, class actions provide an example how liability shifts towards healthcare and safety managers who have more influence on unsafe conditions than

¹¹⁰ *Egglestone v. Barker* [2003] O.J. No. 3137 (S.C.).

¹¹¹ *Ibid* at para 48.

individual physicians and nurses. In addition, class actions receive national media coverage¹¹² and thereby increase public awareness for patient safety.

C. Reporting Systems as a Departure from the Retrospective Focus

Legal procedures address medical error in retrospective. When a lawsuit or a class action is filed, patients have already been hurt. In a way, as James Reason states, the existing forms of error management “firefight” the last error rather than anticipate and prevent the next one.¹¹³ There is actually a whole range of procedures to investigate medical error retrospectively:

- Legal Procedures (civil/criminal)
- Disciplinary Procedures
- Death Investigation (coroner/medical examiner/hospital autopsies)
- Hospital Board Investigations
- Internal Complaint Mechanisms of Healthcare Facilities
- Independent Complaint Mechanisms
- Morbidity & Mortality Conferences
- Peer Review / Quality of Care Committees / Incident Committees
- Public Inquiries

¹¹² CBC News, “Eastern Health can’t win breast cancer lawsuit: premier” April 14, 2008, available online: <<http://www.cbc.ca/canada/newfoundland-labrador/story/2008/04/14/missing-patients.html>>; CBC News, “Lawyers prepare class action for Miramichi patients” February 15, 2008, available online: <<http://www.cbc.ca/health/story/2008/02/15/miramichi-lawsuit.html>>.

¹¹³ James Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate, 1997) at 126.

This shows the dominance of retrospective procedures over forward-looking mechanisms that would enable the healthcare system to use warning signs as a chance to prevent medical error proactively. Error interventions are valuable, but more importantly, latent conditions may be identifiable before errors and accidents occur.¹¹⁴ Many of the emerging reporting systems depart from the retrospective approach, and start proactively finding deficient structures before they lead to medical failures. For this purpose, many reporting systems emphasize the reporting of “near misses” (or “close calls”) and unsafe conditions. Near misses are incidents in which no harm occurs, but an increased risk of accidents was observed. The rationale is that a high number of these “almost-accidents” precede every real medical failure. Medical errors causing harm, so the idea goes, form only the visible tip of an iceberg of unsafe conditions and actions.¹¹⁵ Ideally, reporting systems can predict and foresee where and why the next accident is going to happen and enable managers and staff to prevent it. Reporting system may be able to shift the focus of our attention to the warning signals of accidents that are easily ignored. Near misses and unsafe conditions deserve the attention and investigation that is usually brought up for severe accidents. Many initiatives to establish patient safety reporting systems have been started in different jurisdictions.

¹¹⁴ National Steering Committee on Patient Safety “Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” (2002), available online: <<http://rcpsc.medical.org/publications/>> at 10.

¹¹⁵ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) 87; This correlation of a large number of incidents preceding real accidents is also known as “Heinrich’s Law” referring to a study by H.W. Heinrich in 1931, see Johannes Köbberling, “Das Critical Incident Reporting System (CIRS) als Mittel zur Qualitätsverbesserung in der Medizin“ (2005) 100 Medizinische Klinik 143-8.

IV. Patient Safety Reporting Systems

This part gives an introduction to the confusing variety of reporting systems. It will explain the development the old mandatory reporting systems and the new type of reporting systems. Then, it will outline the recent efforts in the United States towards standardization. It follows a discussion regarding the efficacy of reporting systems. Finally, I will review some of the efforts to protect the confidentiality of reporters.

A. The Variety of Reporting Systems Today

There is a tremendous variety of reporting systems that differ in many aspects, including their purposes, structure and terminology. To start with, one distinction can be made between older mandatory reporting systems and the newer voluntary reporting systems. Mandatory reporting systems existed already before the patient safety movement began. They were set up by the governments on the state-level in the United States and on the provincial level in Canada. Most of these mandatory systems asked for reporting of a list of serious or critical events in hospitals, such as accidental death or loss of limbs. They were designed as an instrument to assure accountability and they are not confidential. The duty to report serious events to state agencies can also be compared to other classical reporting duties of physicians, such as reporting of gunshot wounds or

child abuse.¹¹⁶ Today, many of these old reporting systems were adjusted in response to the patient safety movement to foster both accountability and systems improvements.

The newer, voluntary systems originated mostly out of non-governmental initiatives. They were guided by the systems approach to error and were inspired by reporting systems in other domains, for example by the Aviation Safety Reporting System (1976). Most of the voluntary systems focus exclusively on safety improvements and not accountability. They are non-punitive and protect the confidentiality of the reporter. Some voluntary reporting systems rely entirely on anonymous reporting. Because the focus of voluntary reporting systems lies on finding unsafe conditions, these systems will usually ask for reporting of all adverse events, near misses, and unsafe conditions and not only serious and harmful events.

Reporting systems differ many other ways. One aspect is the different ways they assemble reports: some reporting systems are paper-based and some are web-based. The systems also differ with respect to the specific content of what the healthcare professional have to report. Many systems have their own list of reportable events and their own safety taxonomy. Currently, there are more than 150 different terminology systems in use.¹¹⁷

In some countries, nation-wide reporting systems exist. A nation-wide reporting system was introduced in Australia with the Australian Incident Monitoring System (AIMS). It was initiated by a non-government organization, the Australian Patient Safety

¹¹⁶ An overview of these classical reporting duties for Physicians and Surgeons in Ontario is in the Council of the Ontario College of Physicians and Surgeons' (CPSO) policy "Mandatory Reporting" (Policy #3-05) <<http://www.cpso.on.ca/Policies/mandatory.htm>>.

¹¹⁷ Bryan A. Liang, William Riley, William Rutherford, William Hamman, "The Patient Safety and Quality Improvement Act of 2005: Provisions and Potential Opportunities" (2007) 22 American Journal of Medical Quality 8 at 10.

Foundation (APSF). It operates on a national level as a voluntary system and collects anonymous data about clinical incidents. The reporting system AIMS has now become a product that is sold by Patient Safety International Pty. Ltd., which is the commercial arm of the Australian Patient Safety Foundation.

Denmark has also established a national reporting system administered by the Danish Society for Patient Safety. The reporting of adverse events is mandatory. However, disciplinary proceedings are handled separately from the safety reporting system. England and Wales also have a nation-wide reporting system, the National Reporting and Learning System (NRLS).

In addition, there are various reporting systems in all healthcare systems of the industrialized world that are locally or institutionally organized, or bound to a medical speciality. In Japan, certain hospitals initiated web-based reporting systems.¹¹⁸ Also, certain hospitals in Switzerland have set up reporting systems. From Switzerland, the idea also spread to Germany with the establishment of a voluntary reporting system for certain paediatric hospitals. The reporting system is operated by the Institute for Health Law and Medical Law at the University of Bremen.¹¹⁹ In Germany, there is also a web-based system for ambulatory care.¹²⁰

We can find many of the most remarkable reporting systems in the United States, where the patient safety movement originally began. However, there is no voluntary nation-wide system in the United States. Also, a nation-wide mandatory reporting system

¹¹⁸ K Nakajima, Y Kurata, H Takeda "A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese hospital" (2005) 14 Qual. Saf. Health Care 123-129.

¹¹⁹ Dieter Hart, Kathrin Becker-Schwarze "Risiken verringern – Sicherheit steigern: Ein Critical-Incident-Reporting-System in norddeutschen Kinderkliniken" (2007) 12 Gesundheitsökonomie & Qualitätsmanagement 87-95.

¹²⁰ Jeder Fehler Zählt! <<http://www.jeder-fehler-zaehlt.de/>>.

has not been realized in the United States yet. Only the Sentinel Event Reporting System of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is a nation-wide system that could be described as “mandatory” in the sense that its implementation is an accreditation requirement for hospitals. Recently, the Agency for Healthcare Research and Quality (AHRQ), an agency of the U.S. Department of Health and Human Services, published a list on its website of more than fifty different reporting systems, which it had reviewed.¹²¹ A comprehensive overview of twenty seven state-wide reporting systems in the United States and can be found in the “2007 Guide to State Adverse Event Reporting Systems”¹²². Some reporting systems also exist parallel to each other within the same jurisdiction. In many states, a physician may have the opportunity to report to several different reporting systems. In Pennsylvania, a comprehensive reform coupled the introduction of a reporting system with substantial changes in malpractice insurance.¹²³ A remarkable confidential reporting system is used by the U.S. Department of Veterans Affairs (VA). Their external patient safety reporting system is especially interesting because it is in its design very similar to the forerunner of all voluntary safety reporting systems: the NASA’s Aviation Safety Reporting System (ASRS). In 2000, the VA signed a contract with NASA to develop and operate the Patient Safety Reporting

¹²¹ AHRQ, “Patient Safety Event Reporting Systems Reviewed” <<http://www.pso.ahrq.gov/formats/psersys.htm>>.

¹²² Jill Rosenthal, Mary Takach, “2007 Guide to Adverse Event Reporting Systems”, online at <www.nashp.org>.

¹²³ *Medical Care Availability and Reduction of Error (MCARE) Act (2002), P.L. 154, No. 13 40*, see comments on this complex reform in Clifford A. Rieders, “Pennsylvania’s Patient Safety Authority: An Overview” (2005) 76 *Pennsylvania Bar Association Quarterly* 54-62, Stanton N. Smullens, Adam S. Evans, David B. Nash, “Regulating for Patient Safety: The Law’s Response to Medical Errors: Pennsylvania’s Approach to Reducing Medical Error: The Story of the Patient Safety Authority” (2005) 12 *Widener L. Rev.* 39-52; Carol Brayshaw Longwell, “Pennsylvania’s Patient Safety Authority: Another Perspective” (2005) 63 *Pennsylvania Bar Association Quarterly* 63-72.

System (PSRS) as an external, voluntary, and confidential safety reporting system. NASA, who had already operated the Aviation Safety Reporting System (ASRS) successfully, considered that a similar system would be feasible in healthcare. NASA hired a team of expert analysts with professional medical experience and set up a special office for the reporting system in California.

B. Questions regarding Jurisdiction and State Responsibility

Reporting systems will face many different challenges in establishing their structure in different jurisdictions of the world. It will be important to determine carefully in each jurisdiction to which jurisdictional subject matter those reporting systems belong. Are reporting systems a matter of “healthcare” or are they rather “research”? If safety work is deemed “research” rather than the improvement of healthcare quality, it places it, in some jurisdictions, into a different legal realm.¹²⁴ This can be crucial in the United States for example because existing regulation regarding the protection of research information may apply.¹²⁵ Reporting systems are also connected to regulation of the healthcare profession and, if privately established, a matter of private law. Statutory evidentiary privileges suggest that reporting systems touch both on public and private law. Evidentiary privileges foster a public goal (patient safety) while affecting private litigation at the same time.

¹²⁴ Bryan A. Liang, “Regulating for Patient Safety: The Law’s Response to Medical Errors: Collaborating on Patient Safety: Legal Concerns and Policy Requirements” (2005) 12 *Widener L. Rev.* 83 at 91.

¹²⁵ *Ibid.*

It is also necessary to inquire whether reporting systems interfere with other jurisdictional subject matters. There may be tasks and functions that the reporting system is not suited for and incidents that should not be reported. From the very start, “intentional crimes” were excluded from reporting to the forerunner of patient safety reporting systems, the Aviation Safety Reporting System (ASRS). There is a tension between the efforts to gather confidential observations and the control of regulatory agencies (in this case the FAA) and public prosecution agencies. From a safety perspective, it would be reasonable to report crimes as well. The safety of a patient can be compromised by unintentional errors as well as by deliberate injuries. There may actually be a very high number of undetected crimes in the hospital setting considering the vulnerability of patients. However, it is correct to exclude intentional crimes from reporting because crime-detection and prosecution is an essential task of prosecution agencies. Protecting the confidentiality of the reporter does only work insofar as the public accepts it. In case of deliberate crimes, the need for vengeance and punishment will easily outweigh sophisticated safety efforts based on the “systems approach”. Reporting forms have to contain the instruction to report all intentional crimes to prosecution agencies. Keeping this balance was also emphasized by Senator Edward Kennedy in the debate regarding the newly established privilege of Patient Safety and Quality Improvement Act of 2005: “[D]rawing the boundaries of this privilege requires a careful balance, and I believe the legislation has found that balance. The bill is intended to make medical professionals feel secure in reporting errors without fear of punishment,

and it is right to do so. But the bill tries to do so carefully, so that it does not accidentally shield persons who have negligently or intentionally caused harm to patients.”¹²⁶

C. Trends toward Standardization in the United States

Recent efforts in the United States aim towards standardization that is urgently needed. Already in 1999, the IOM recommended a nationwide mandatory reporting system that would require all health care organizations to report on a defined list of adverse events that result in death or serious harm.¹²⁷ At the same time, the IOM encouraged the development of voluntary reporting systems.¹²⁸ A later report of the IOM in 2004 titled *Patient Safety: Achieving a New Standard of Care* gave an overview over the essential operational features of reporting systems.¹²⁹ Also, the World Health Organization (WHO) developed the “Draft Guidelines for Adverse Event Reporting and Learning Systems” in 2005 to outline the features of voluntary reporting systems.¹³⁰

Most important for the current standardization efforts is the federal *Patient Safety and Quality Improvement Act of 2005* amending the *Public Health Service Act*.¹³¹ The

¹²⁶ Senator Edward Kennedy, Congressional Record, July 21st 2005, Section 43, speech on the Patient Safety and Quality Improvement Act 2005; available online: <<http://www.govtrack.us/congress/record.xpd?id=109-s20050721-43&bill=s109-544>>.

¹²⁷ Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) “To Err is Human – Building a Safer Health System” (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) at 87 recommendation 5.1.

¹²⁸ *Ibid.* at 89 recommendation 5.2.

¹²⁹ Philip Aspden, Janet M. Corrigan, Julie Wolcott, Shari M. Erickson, (eds.) “Patient Safety – Achieving A New Standard For Care” (Committee on Data Standards for Patient Safety) (Washington D.C.: National Academy Press 2004).

¹³⁰ World Health Organization (WHO), World Alliance for Patient Safety “WHO Draft Guidelines for Adverse Event Reporting and Learning Systems” (2005), available online: <www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf>.

¹³¹ *Patient Safety and Quality Improvement Act of 2005*, S. 544 [109th]; William Riley, Bryan A. Liang, William Rutherford, William Hamman, “The Patient Safety and Quality Improvement Act of 2005:

Act does not create a new federal agency for patient safety but it creates a general framework, a form of meta-regulation for all types of reporting systems in the U.S. both public and private. S. 924 is a centerpiece of the new act because it addresses the certification and listing of patient safety organizations (PSOs). The *Patient Safety and Quality Improvement Act* allows patient safety organizations to be public or private entities. They can also be for-profit organizations. In order to gain the trust of reporters, such an organization should ideally be free from any doubt about their neutrality. The *Patient Safety and Quality Improvement Act* does not allow health insurance companies to become patient safety organizations according to s. 924 (b) (D).¹³² A further challenge is the creation of a coherent terminology and safety taxonomy.¹³³ Standardized reporting forms are now available as part of the AHRQ Common Formats for Patient Safety Organizations.¹³⁴

Developing an Error Reporting System to Improve Patient Safety” (2008) 4 Journal of Patient Safety 13-17; Bryan A. Liang, William Riley, William Rutherford, William Hamman “The Patient Safety and Quality Improvement Act of 2005: Provisions and Potential Opportunities” (2007) 22 American Journal of Medical Quality 8-12; Carolyn M. Clancy, “New Patient Safety Organizations Lower Roadblocks to Medical Error Reporting” (2008) 23 American Journal 318-321; Barry R. Furrow, “Regulating for Patient Safety: The Law’s Response to Medical Errors: Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction” (2005) 12 Widener L. Rev. 1-38 at 16.

¹³² *Patient Safety and Quality Improvement Act of 2005*, S. 544 [109th].

¹³³ Andrew Chang, Paul M. Schyve, Richard J. Croteau, Dennis S. O’Leary, Jerod M. Loeb, “The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events” (2005) International Journal for Quality in Health Care 1-11, see also Saul N. Weingart, “Beyond Babel: prospects for a universal patient safety taxonomy” (2005) 17 International Journal for Quality in Health Care 93-94.

¹³⁴ AHRQ Common Formats for Patient Safety Organizations, Version 0.1 Beta Release- August 2008, available online at <<http://www.ahrq.gov/>>.

D. Questions regarding Efficacy, Cost-Benefit Analysis, and Side-Effects

The economic analysis of law becomes increasingly important in health law.¹³⁵

There is a growing demand to assemble evidence for the efficacy and efficiency of regulation. A symbolic value of regulation is not considered sufficient. Plausibility and sound reasoning alone seem to not suffice either, especially when it comes to cost-intensive regulation. Similar to the development in medicine towards “evidence-based medicine” (EBM), there is growing idea of “evidence-based law”, or “evidence-based regulation”.¹³⁶

1. Efficacy and Cost-Benefit Analysis of Reporting Systems

Do reporting systems work? While the concept of reporting systems seems rational, there is little evidence on whether reporting systems have a measurable effect on adverse events rates and medical error.¹³⁷ In 2005, Maxine M. Harrington reviewed if

¹³⁵ Michelle M. Mello, Carly N. Kelly, Troyen A. Brennan “Fostering Rational Regulation of Patient Safety”¹³⁵ (2005) 30 *Journal of Health Politics, Policy and Law* 375-426, see also: Don Dewees, David Duff, Michael Trebilcock, *Exploring the Domain of Accident Law – Taking the Facts Seriously* (Oxford: Oxford University Press, 1996), see its preface and chapter 3 “Medical Accidents” at 95.

¹³⁶ Michelle M. Mello, Carly N. Kelly, Troyen A. Brennan “Fostering Rational Regulation of Patient Safety”¹³⁶ (2005) 30 *Journal of Health Politics, Policy and Law* 375-426.

¹³⁷ Jocelyn Downie, William Lahey, Don Ford, Elaine Gibson, Mary Thomson, Tom Ward, Fiona McDonald, Alison Shea “Patient Safety Law: From Silos to Systems” (2006), available online: <<http://www.patientsafetylaw.ca/>> at 16 of Appendix 1.

reporting systems have made a difference five years after the IOM report and her finding was sceptical:

“[A]s currently implemented, most reporting systems are not able to identify medical error or monitor progress in the prevention of error. The full magnitude of the problem is still unknown and no one knows how many errors exist that are not being reported or whether reporting has had any positive impact on patient safety.”

The evaluation is difficult because the effects depend on a whole range of factors regarding the context of a reporting system. The context encompasses the specific structure of the reporting system (feedback mechanism etc.), its legal framework and protections, and also its underlying professional, linguistic, national and regional culture.¹³⁸ The Canadian Medical Protective Association states correctly that “[t]here are no plug and play solutions that are easily transportable from one jurisdiction to another.”¹³⁹

It is unlikely that there will be an immediate change in patient outcomes shortly after the establishment of a reporting system. The number of injured patients in hospitals will not drop automatically. The rationale of reporting systems is to take unsafe conditions more seriously, gather observations and create awareness for frequently occurring errors that allow informed changes in healthcare in the future. Possibly, there won't be a constant and steady progress in patient safety because reporting systems rely in part on an unspecific hope that the data will lead to innovations and new solutions to

¹³⁸ The impact of culture on safety is emphasized by Robert L. Helmreich, Ashleigh C. Merrit, *Culture at Work in Aviation and Medicine – National, Organizational and Professional Influences* (Aldershot: Ashgate, 1998).

¹³⁹ The Canadian Medical Protective Association, “Medical liability practices in Canada: Towards the right balance” (2005) available online: <<https://www.cmpa-acpm.ca>> at 4 and 13.

reduce certain types of adverse events. For a long time, no visible changes may occur. Then maybe, research may lead occasionally to specific improvements in safety because innovations may be found to address a frequent error. In addition, there may be positive effects on how medicine is practised because of increased awareness for safety issues and because of feedback to the reporters. In a very small survey regarding the Australian Incident Monitoring System (AIMS), 10 out of 12 respondents (83%) reported that AIMS investigations resulted in significant changes to equipment usage, medication prescribing or administration, and clinical protocols.¹⁴⁰ Also, examples of reporting systems in other industries show visible successes in the long run. The forerunner of all safety reporting systems, the Aviation Safety Reporting System (ASRS), has been administered by NASA since 1976 and it is still in operation today.¹⁴¹ The Federal Aviation Administration (FAA) wanted to eliminate unsafe conditions in the national aviation system and prevent avoidable accidents.¹⁴² It asked the National Aeronautics and Space Administration (NASA) to administer the program as an independent third party.¹⁴³ On the system's 25th anniversary in 2001, over 558,000 incident reports had been processed and safety in aviation has increased during this time-period.¹⁴⁴ There are many similarities of aviation and medicine. Both domains are complex and hazardous, and use high-technology. Also, regulation and hierarchical structures, intense pressure,

¹⁴⁰ Allan D. Spigelman, Judith Swan, "Review of the Australian Incident Monitoring System" (2005) 75 ANZ J. Surg. 657-661.

¹⁴¹ ASRS research paper no. 60, "ASRS: The Case for Confidential Incident Reporting Systems" (2001), available online: <<http://asrs.arc.nasa.gov/publications/research.html>>, 1.

¹⁴² *Ibid.*

¹⁴³ *Ibid.*

¹⁴⁴ *Ibid.*

and long working hours characterize both domains.¹⁴⁵ But, there are also fundamental differences between aviation and healthcare that require caution not to expect similar results.¹⁴⁶ Pilots, being the reporters in aviation safety, are in the same position as their passengers and cargo. Aviation safety equals “workplace safety” and “occupational safety” for pilots because a flight accident affects the whole airplane. Therefore, safety work is important for a pilot’s personal safety. This is different in medicine. Physicians are at risk of hazards at their workplace too (infections etc.). However, the risks that physicians experience are fundamentally different from that of their patients. Pilots will want to get involved in safety improvements for their own safety more readily. In medicine, it might be necessary to require mandatory reporting or add further incentives for healthcare professionals to report unsafe conditions.

There are further doubts regarding the efficiency and cost-benefit analysis of reporting systems. Michelle M. Mello, Carly N. Kelly, and Troyen A. Brennan state in their article “Fostering Rational Regulation of Patient Safety”¹⁴⁷:

“[W]e believe that a regulatory intervention is rational if it is cost effective—that is, if it is based on the best available evidence that the benefits of compliance outweigh the costs. We believe that a regulatory framework is rational if it achieves cost-effective safety gains in a manner that minimizes costs, waste, and negative externalities and permits regulatory flexibility in response to variations in health care settings, markets, and cultures.”

¹⁴⁵ R. Randell, “Medicine and Aviation: A Review of the Comparison” (2003) 42 *Methods Inf Med* 433-6 at 436.

¹⁴⁶ *Ibid.*

¹⁴⁷ Michelle M. Mello, Carly N. Kelly, and Troyen A. Brennan “Fostering Rational Regulation of Patient Safety”¹⁴⁷ (2005) 30 *Journal of Health Politics, Policy and Law* 375-426.

Do the assumed benefits that are associated with the reporting system actually justify the investment of time and money? Or would it be better to invest into additional healthcare services, safety or other social services, or even to return the money to the taxpayers? Similar arguments and doubts exist with respect to the introduction of a no-fault compensation scheme for medical accidents. In a tax-financed healthcare system, the question arises whether the money should be spent on financing further healthcare services and eliminating waiting times before indemnifying those who received healthcare and were harmed by it. The issue of cost-benefit analysis is complex because there is a whole range of alternative means of patient safety research, such as chart review, inspections and other instruments of monitoring and surveillance. Similar to flight-recorders in aviation, one could imagine surgery-recorders or cameras for safety surveillance.¹⁴⁸ Patient safety data could also be improved by a better system of death certification and investigation,¹⁴⁹ allowing coroners to investigate in case of hospital deaths more thoroughly. Recently, many death investigation systems (coroners or medical examiners) have been subject to reforms in certain jurisdictions to improve their beneficial effect for public health and patient safety.

These questions about the allocation of scarce resources require more research. Scholars of economics, healthcare, and the law may have to conduct research together to find answers. A close monitoring of the costs and benefits of reporting systems in foreign healthcare systems might also be an option for those jurisdictions that have not yet

¹⁴⁸ R. Randell, "Medicine and Aviation: A Review of the Comparison" (2003) 42 *Methods Inf Med* 433-6 at 436.

¹⁴⁹ Don Dewees, David Duff, Michael Trebilcock, *Exploring the Domain of Accident Law – Taking the Facts Seriously* (Oxford: Oxford University Press, 1996) at 135.

decided to implement reporting systems.¹⁵⁰ However, the different contexts and cultures require a lot of caution. It may often be erroneous to search for “silver bullets” in foreign jurisdictions.

2. Side-Effects of Reporting and Fines for Intentional Misuse

Information collected by a reporting system can influence important decisions of by healthcare management and administration, especially regarding the purchase of medical equipment. The following example from a reporting system in Germany might illustrate that: nurses at a paediatric hospital had repeatedly reported that certain ventilation tubes slipped out of the tracheas of children. It turned out that the hospital had recently changed their supplier of a specific tape to hold the tubes. The new type of tape was not as strong as the previous type, which caused the tubes to slip out. In reaction to these occurrences, the hospital re-ordered the previous type of tape again. This example shows that reporting systems have the ability to influence decisions to buy equipment and to allocate resources. At the same time, this creates an opportunity for misuse and manipulation. It would distort the rationales of the reporting system, if manufacturers of medical equipment would discover the reporting system as a marketing tool. Fines for misuse and manipulative reporting may become an important issue in the future. This

¹⁵⁰ Joan M. Gilmour “Patient Safety, Medical Error and Tort Law: An International Comparison, Final Report May 2006”, available online at: <http://www.osgoode.yorku.ca/faculty/Gilmour_Joan_M.html> vii, see Recommendation 1.3 “Patient safety initiatives such as error reporting systems must be monitored and evaluated to assess their results in improving care, communication and outcomes.”

would not be an uncommon concept: Fines for the misuse of other types of safety equipment (life vests, emergency alarms etc.) are well known.

E. Protections for Reporting and the Uncoupling of Reporting Systems

A key-concept of many voluntary reporting systems is that they are non-punitive to enable healthcare professionals to report their concerns without the fear of repressions. This aspect is closely linked to the necessity of confidentiality because its potential sanctions can come from many different sides. An example of a sanction could be a disciplinary process or it could also be the employer imposing negative sanctions on their own. It could also be a complaint from a patient or a lawsuit threatening the physician's or nurse's reputation. In North American jurisdictions, the legal discovery is the biggest threat for reporters. Legal (pre-trial) discovery is a mechanism whereby the parties in a lawsuit may force one another to provide all relevant information that is not protected by evidentiary privilege. A reporting system can become a perfect "lawsuit kit"¹⁵¹ if reports are not protected from discovery.

1. Practical Solutions

There is a variety of practical ways to protect reporters and to shield reports from legal discovery.¹⁵² One is to rely entirely on anonymous reporting. However, anonymous

¹⁵¹ Brian A. Liang, "Risks of Reporting Sentinel Events" (2000) 19 Health Affairs 112-120 at 112.

¹⁵² Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, (editors) "To Err is Human – Building a Safer Health System" (Committee on Quality of Health Care in America, Institute of Medicine) (Washington D.C.: National Academy Press, 2000) 124-127.

reporting can create difficulties for feedback mechanisms, follow-up and root-cause analysis. A different method is de-identification.¹⁵³ Reporters give their name when reporting. However, after all questions have been answered, feedback has been provided, and the follow-up is complete, the name and further information about the reporter will be deleted.¹⁵⁴ This mechanism reduces the risk of discovery to the early time-period after reporting. An interesting third method has been developed for web-based reporting systems: The reporter reports anonymously and receives a file-number and password for his report. He can then access his report-file online and receive feedback information in a confidential way. In addition, safety analysts can also post questions and communicate with the reporter confidentially.

2. Legal Protections

The new *Patient Safety and Quality Improvement Act* in the U.S. contains three important provisions to protect reports and reporters legally in s. 922: evidentiary privilege, a prohibition of adverse employment actions, and a provision for civil monetary penalties of up to \$ 10,000 for knowingly disclosures of a so called “identifiable patient safety work product”. The evidentiary privilege protects the “patient safety work product”, defined broadly as any data, reports, records, memoranda, analyses, or written or oral statements assembled for reporting. According to the act, this does not include a patient’s medical record, billing and discharge information, or any other

¹⁵³ *Ibid.* at 126.

¹⁵⁴ *Ibid.*

original patient or provider record. An exception of the privilege exists for criminal proceedings, but only after a court makes an in camera determination that the patient safety work product contains evidence of a criminal act and that the information is not “reasonably available” from any other source. The major challenge seems to be how to control and manage the reported information carefully. Enacting these legal protections can be compared to creating “firewalls”¹⁵⁵ or “dams” between information gathered by the reporting systems on the one side, and different procedures serving accountability on the other side. Whether this attempt to uncouple reporting systems from other procedures will be successful depends on the judiciary, who usually disfavours evidentiary privileges and interprets them narrowly,¹⁵⁶ and the practical limitations of “protecting” information. While it is the aim of the *Patient Safety and Quality Improvement Act* to protect the confidentiality of information that could identify the reporter, it facilitates at the same time the creation of a “Network of Patient Safety Databases” (s. 923) so that the healthcare system as a whole may learn from shared patient safety data to find and fight unsafe conditions.

¹⁵⁵ The Canadian Medical Protective Association, “Medical liability practices in Canada: Towards the right balance” (2005) available online: <<https://www.cmpa-acpm.ca>> at 19.

¹⁵⁶ Bryan A. Liang “Legal Concerns in Patient Safety: The Need for Regulatory Action” (2008) 4 J. Patient Saf. 51-53 referring to the recent case of *Bethel v. U.S. ex rel Veterans Administrative Medical Center of Denver*, CO, 242 F.R.D. 580 (D. Colo 2007) in which “virtually all patient safety materials [of a VA Medical Center] were discoverable” despite a specific federal provision protecting designated documents of the VA from discovery. On a positive note, one report of a nurse was considered privileged in this decision. It seems that the new privilege established by the new *Patient Safety and Quality Improvement Act* provides even stronger protection.

V. Conclusions

The present “systems approach” to medical error has conceptual limitations. The theoretical model of human error has to be re-considered carefully from time to time. The critique with respect to tort-based medical malpractice systems persists. Disclosure of medical errors to patients is still difficult and requires substantial legal changes. Either legal sanctions for non-disclosure or a reform of the compensation issue towards an administrative no-fault insurance system or cooperative compensation fund would foster the disclosure of medical errors. The paper then went on to show that class actions are a powerful tool to shed light on systemic deficiencies and create public awareness for patient safety. Patient safety reporting systems, which may be able to address unsafe conditions proactively, exist in a variety of forms today. Efforts towards standardization and stronger protections for reporters are underway in the United States. However, doubts about the efficacy of reporting systems require further research.

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